II. REMARKS

A. State of the Claims

Claims 50-67 and 82-84 were pending at the time of the Office Action, with claims 33-49 having been withdrawn from consideration at this time as being drawn to a non-elected invention. Claims 50, 53, 56, 64, and 82 have been amended in the Amendment set forth herein. Written description support for the claim amendments can be found generally throughout the specification, such as in the claims as originally filed. Claim 52 has been canceled without prejudice or disclaimer. Applicants reserve the right to prosecute any of the subject matter that has been canceled from the claims in a divisional or continuation application. No new claims have been added. Thus, claims 33-51, 53-67 and 82-84 are presently under consideration.

B. The Rejection Under 35 U.S.C. §101 have been Overcome

Claim 64 has been rejected under 35 U.S.C. §101 because the claimed invention is alleged to be directed to nonstatutory subject matter. Applicants traverse.

Claim 64, as it is currently written, recites "a recombinant host cell." Written description support for "a recombinant host cell" can be found throughout the specification, such as in paragraph [0135]. In view of this amendment, the subject matter set forth in claim 64 is sufficiently distinguished over cells as they naturally exist. Therefore, the rejection under 35 U.S.C. §101 has been overcome.

C. The Written Description Rejections Under 35 U.S.C. §112, First Paragraph, have been Overcome

Claims 50, 51, 57, 61-64, and 66 have been rejected under 35 U.S.C. §112, first paragraph, as failing to comply with the written description requirement. The Action alleges that the specification does not provide sufficient written description of each claimed genus because of

recitation of an insufficient number of members of each claimed genus. Applicants respectfully traverse.

The Federal Circuit has stated that the test for the written description requirement is "whether the application relied upon 'reasonably conveys to the artisan that the inventor had possession'" of the claimed subject matter. *In re Daniels*, 144 F.3d 1452, 1456, 46 USPQ2d 1788, 1790 (Fed. Cir. 1998). See also *Markman v. Westview Instruments, Inc.* 52 F.3d 967, 34 USPQ 2d 1321 (Fed. Cir. 1995) (en banc) ("Claims must be read in view of the specification, of which they are a part.").

Claim 50 as currently written recites the limitation "wherein the nucleic acid comprises a polynucleotide region comprising at least 90% nucleotide identity with the nucleic acid sequences of SEQ ID NO. 1 or SEQ ID NO. 2, or a polynucleotide with a complementary sequence." Claim 50 as written includes the limitations of claim 52, which, although canceled in the Amendment set forth herein, was considered enabled by the Examiner. The remaining claims at issue in this rejection depend from claim 50. Thus, by virtue of the fact that claim 50 now includes the limitations of claim 52, this rejection has been overcome.

Because the specification as written reasonably conveys to those of ordinary skill in the art that the inventors had possession of the claimed subject matter at the time the invention was made, the written description requirement has been satisfied. Therefore, it is requested that the rejection of claims 50, 51, 57, 61-64, and 66 under 35 U.S.C. §112, first paragraph, should be withdrawn.

D. The Enablement Rejections Under 35 U.S.C. §112, First Paragraph, have been Overcome

1. Claims 52-67 and 82-84

Claims 52-67 and 82-84 have been rejected under 35 U.S.C. §112, first paragraph, as not sufficiently enabled by the specification. In particular, the Action indicates that while the specification is enabling for the recombinant polynucleotides consisting of SEQ ID NO:1 and SEQ ID NO:2, the recombinant polynucleotide consisting of SEQ ID NO: 5 and SEQ ID NO:3, the recombinant polynucleotide encoding the amino acid sequences of SEQ ID NO:6 and SEQ ID NO:7, and the recombinant polynucleotide encoding the amino acid sequence of SEQ ID NO:4, it is asserted that the specification does not reasonably provide enablement for any other embodiments. Applicants traverse

The standard for the test of enablement is "whether one reasonably skilled in the art could make or use the invention from the disclosure in the patent application coupled with information known in the art without undue experimentation." *Manual of Patent Examining Procedure (MPEP)* §2164.01, citing *United States v. Telectronics, Inc.*, 857 F.2d 778, 785, 8 USPQ2d 1217, 1223 (Fed. Cir. 1988).

Applicants note that the entire specification as written gives full guidance to those of skill in the art to carry out the claims as for the entire scope which is claimed. For example, the nucleotide sequences of SEQ ID NOs. 1-4 and SEQ ID NOs. 6-8, are fully disclosed in the instant specification. Paragraphs [0057] through [0124] provide substantial detail regarding the structure and function of the recombinant nucleic acid molecules set forth in claims 53-67. Synthesis of any one of the recombinant nucleic acid molecules that are encompassed by the claims can be carried out any one of a variety of well-known methods for nucleic acid synthesis that were available at the time the invention was made.

Further, the specification provides full guidance for assaying every nucleic acid sequence for glycerol dehydatase independent from co-enzyme B12 (see, e.g., paragraphs 0181] – [0245]).

As to claims 82-84, the specification also provides substantial detail regarding the production of polypeptides encoded by a recombinant nucleic acid coding for at least one subunit of a glycerol dehydratase, wherein the catalytic activity of the glycerol dehydratase is not dependent on coenzyme B12. For example, as to independent claim 82, SEQ ID NOs 4-8 are disclosed in the specification. Paragraphs [0142]-[0170] provides detailed information regarding the structure and process for production of polypeptides encoding for a recombinant nucleic acid coding for at least one subunit of a glycerol dehydratase in the manner set forth in claim 82. Further, one of ordinary skill in the art would be familiar with the numerous techniques pertaining to production of polypeptides from recombinant nucleic acids that were known to those of ordinary skill in the art at the time of the priority date of the instant invention.

In conclusion, one reasonably skilled in the art could not make and use the claimed invention would be able to make and use the claimed invention without an undue amount of experimentation. The Examiner has presented no evidence to doubt the sufficiency of the disclosure. Therefore, it is respectfully requested that the enablement rejections under 35 U.S.C. §112, first paragraph, should be withdrawn.

2. Claim 65 and Statement

Claim 65 has been rejected under 35 U.S.C. §112, first paragraph, as containing subject matter which was not described in the specification as to enable one skilled in the art to make and/or use the invention without an undue amount of experimentation. Claim 65 recites " [t]he recombinant nucleic acid of claim 61, wherein the host cell is an *Escherichia coli* strain filed at the National Collection of Cultures of Micro-organisms (NCCM) on June 24, 1999 under the

access No. I-2243." The Action asserts that Applicants' disclosure in the specification is insufficient assurance that the conditions of 37 C.F.R. §1.801-1.809 have been met.

As suggested by the Examiner and in accordance with the requirements under 37 C.F.R. §1.801-1.809 and MPEP §2402-2411.05, I, Mark B. Wilson, attorney of record for Applicants, provide the following statement:

> The *Escherichia coli* strain set forth in claim 65 has been deposited at the National Collection of Cultures of Micro-organisms (NCCM) on June 24, 1999, in accordance with the terms of the Budapest Treaty. The access No. is I-2243. The deposit has been made under the terms of the Budapest Treaty, and the strain will be irrevocably and without condition released to the public upon issuance of the patent. Evidence of the accessibility of the strain of Escherichia coli as set forth above is provided in the form of the attached copy of the contract with the above mentioned depository with respect to the deposited strain, which is attached as Exhibit 1.
>
> During the pendency of this application, access to the invention will be afforded to the Commissioner upon request. All restriction upon availability to the public will be irrevocably removed upon granting of the patent. The deposit will be maintained at a public repository for a period of 30 years or 5 years after the last request or for the effective life of the patent, whichever is longer. Further, the deposit will be replaced if it should ever become inviable.

3. Conclusion

In view of the above, the enablement rejections under 35 U.S.C. §112, first paragraph, have been overcome. Therefore, it is requested that the rejections should be withdrawn.

BEST AVAILABLE COPY

TRAITE DE BUDAPEST SUR LA RECONNAISSANCE
INTERNATIONALE DU DEPOT DES MICRO-ORGANISMES
AUX FINS DE LA PROCEDURE EN MATIERE DE BREVETS

FORMULE INTERNATIONALE

DESTINATAIRE :

INSTITUT NATIONAL de la
RECHERCHE AGRONOMIQUE
147, rue de l'Université
75338 PARIS CEDEX 07

NOM ET ADRESSE
DU DEPOSANT

RECEPISSE EN CAS DE DEPOT INITIAL,
délivré en vertu de la règle 7.1 par
l'AUTORITE DE DEPOT INTERNATIONALE
identifiée au bas de cette page

I. IDENTIFICATION DU MICRO-ORGANISME

Référence d'identification donnée par le DEPOSANT :	Numéro d'ordre attribué par l'AUTORITE DE DEPOT INTERNATIONALE :
DH5α (pSPD5)	I - 2243

II. DESCRIPTION SCIENTIFIQUE ET/OU DESIGNATION TAXONOMIQUE PROPOSEE

Le micro-organisme identifié sous chiffre I était accompagné :

☐ d'une description scientifique

☐ d'une désignation taxonomique proposée

(Cocher ce qui convient)

III. RECEPTION ET ACCEPTATION

La présente autorité de dépôt internationale accepte le micro-organisme identifié sous chiffre I, qu'elle a reçu le 24 JUIN 1999 (date du dépôt initial) [1]

IV. RECEPTION D'UNE REQUETE EN CONVERSION

La présente autorité de dépôt internationale a reçu le micro-organisme identifié sous chiffre I le (date du dépôt initial)
et a reçu une requête en conversion du dépôt initial en dépôt conforme au Traité de Budapest le (date de réception de la requête en conversion)

V. AUTORITE DE DEPOT INTERNATIONALE

Nom :	Signature(s) de la (des) personne(s) compétente(s) pour représenter l'autorité de dépôt internationale ou de l'(des) employé(s) autorisé(s) :
CNCM Collection Nationale de Cultures de Microorganismes	Simona OZDEN Directeur de la CNCM
Adresse : INSTITUT PASTEUR 28, Rue du Docteur Roux F-75724 PARIS CEDEX 15	Date : Paris, le 23 septembre 1999

1 En cas d'application de la règle 6.4.d), cette date est la date à laquelle le statut d'autorité de dépôt internationale a été acquis.